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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHIN, CHRISTOPHER L	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 07/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/820,974	Friesen et al
Examiner	**Art Unit**
Chris Chin	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *35-57* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *35-57* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. *06/808,563*.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Reissue Applications

1. The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

2. Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 4,861,711 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

3. The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

The reissue oath/declaration was signed in 1996. A more recent reissue oath/declaration is required.

4. In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Claims 35-57 are rejected as being based upon a defective reissue oath/declaration under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defect is set forth above.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251.

5. Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

6. The amendment filed 3/30/01 proposes amendments to the first line of the specification to include the parent application that do not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. A supplemental paper correctly amending the reissue application is required.

A shortened statutory period for reply to this letter is set to expire ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this letter.

7. Claims 35-57 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d

1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

8. Applicants are advised to provide a PTOL-1449 with all of the references cited in the parent applications.

9. A certification of correction was filed in U.S. Patent 4,861,711. However, the corrections listed in the certification of correction have not been inserted into the claims of this reissue - see MPEP 1411.01.

Claim Rejections - 35 U.S.C. § 112

10. Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44, line 4, the term "chromathographic" is misspelled.

Claim Rejections - 35 U.S.C. § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 35, 38, 43, 44, 45, 48, 49, and 50 are rejected under 35 U.S.C. 102(b) as being anticipates by Deutsch et al.

Deutsch et al (U.S. Patent 4,094,647) discloses a chromatographic test device for performing immunoassays. The test device comprises an elongated strip element composed of a material capable of transporting a developing fluid longitudinally there long by capillarity. The strip element has a portion designated or marked for receiving the sample to be tested and is incorporated at one or more portions with reagent means comprising one or more reagent constituents. The sequence of the various reagent constituent incorporated portions of the strip element and the sample receiving portion thereof, as well as the spacing therebetween, is established such that upon complete traversal of the strip element by the developing fluid, a detectable response which is a function of the characteristic under determination is disposed at a predetermined measuring location on the strip element (col. 2, line 58, through col. 3, line 22).

Looking at Figs. 1 and 2, a test device is shown comprising a strip element (11) composed of an absorbent material. Strip element (11) has a beginning end portion (12) and a terminal end portion (16). A sample receiving portion (13) is designated by appropriate marking means such as a dried spot of a dye solution. Portions (14) and (15) are incorporated with appropriate constituents of a reagent means selected for detecting a particular characteristic of a test sample. In use, the sample is applied to sample receiving portion (13) and the beginning end portion (12) is immersed in the developing fluid which then begins to advance along the strip element (11). When the leading front of the developing fluid reaches terminal end portion (16), a detectable response is detected at portion (15). The response (fluorescence, light absorbance, or radioactivity) is measured by appropriate means (col. 3, line 57, through col. 4, line 16). In one embodiment of the test device, an antibody is immobilized in portion (15) and portion (14) contains a mobile labeled antigen (a ligand or a binding analog thereof) (col. 4, lines 35-64). Label reagents for use in the disclosed test device include fluorescent labels (col. 8, lines 65-68). The disclosed test device can be used to detect hormone analytes, such as chorionic gonadotropin (col. 9, lines 13-26). Preparation of the strip element (11) is taught in columns 10-11. After application of reagents to specific portions of strip element (11), the strip is allowed to dry at room temperature (i.e. the reagents are present in dehydrated form) (col. 11, line 15).

Looking at Figure 1, the portion of strip element (11) between portion (12) and portion (14) is considered a mobile phase application zone (MPAZ). Between portion (14) and portion (16) is considered a single intermediate zone (IZ). Portion (16) is considered to be an absorption

zone (AZ). In the IZ of the disclosed test device is portion (14) which contains a mobilizable labeled reagent and is considered a single solid phase zone (SPZ).

13. Claims 35, 43-45, 48, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Count 2 from the interference proceedings.

Count 2 recites:

--A process for the detection or determination of a component in a fluid wherein said component is an analyte with bioaffinity binding properties by rehydrating or solvating reactants and reagents by the fluid containing the analyte or by an additional fluid, said reactants and reagents being present in a dehydrated state in an analytical device for the detection or determination of a component in a fluid wherein said component is an analyte with bioaffinity binding properties, comprising a layer of a plurality of substantially planar zones adjacent one another and in absorbent contact with one another, said layer including:

a mobile phase application zone (MPAZ), an intermediate zone (IZ) and an adsorption zone (AZ), liquid being capable of moving by adsorption from said MPAZ through said IZ to said AZ, and wherein said IZ further comprises a solid phase zone (SPZ) having at least one unlabeled reactant, capable of interactions of biological affinity with at least one analyte;

at least one unattached, labeled reactant (conjugate), capable of interactions of biological affinity with said at least one analyte, disposed in an area between the MPAZ and the SPZ; and

an analyte application zone disposed at said MPAZ or in between said MPAZ and said AZ, said process comprising:

applying a sample to said analyte application zone, reacting the at least one analyte in the sample in said layer and detecting said at least one analyte in said layer.--

Claim Rejections - 35 U.S.C. § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 35, 36, 38, 40, 42-45, and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Count 1 from the interference proceedings in view of Deutsch et al or Weng et al or Giegel et al or Rupchock et al.

Count 1 recites:

--An analytical device for the detection or determination of a component in a fluid wherein said component is an analyte with bioaffinity binding properties, comprising a layers of a plurality of substantially planar zones adjacent one another and in absorbent contact with one another, said layer including:

a mobile phase application zone (MPAZ), an intermediate zone (IZ) and an adsorption zone (AZ), liquid being capable of moving by adsorption from said MPAZ through said IZ to said AZ, and wherein said IZ further comprises a solid phase zone (SPZ) having at least one unlabeled reactant, capable of interactions of biological affinity with at least one analyte;

at least one unattached, labeled reactant (conjugate) capable of interactions of biological affinity with said at least one analyte, disposed in an area between the MPAZ and the SPZ; and

an analyte application zone disposed at said MPAZ or in between said MPAZ and said AZ, wherein after application of said at least one analyte, said at least one analyte is reaction with said reactants in said layer and is detected in said layer.--

Count 1 differs from the instantly claimed invention in failing to teach dehydrating the reagents in the specific zones of the claimed device, utilizing antigens and antibody reagents for the detection of analyte antigen, and the use of enzyme labels in the labeled reactant.

See above for the teachings of Deutsch et al.

Weng et al (U.S. Patent 4,740,468) discloses a test strip device for performing immunoassays. The device is a strip of bibulous material capable of being traversed by a test solution through capillary migration. The test solution is comprised of the sample and a first member of a specific binding pair (sbp member) capable of binding the analyte. The strip contains, integral therewith, a second sbp member for concentrating and non-diffusively binding the first sbp member at a small situs on the strip separate from an end portion of the strip provided for contacting the test solution. Generally, the second sbp member binds to a complex

formed from the binding of analyte to the first sbp member. A detectible signal is produced by means of a signal producing system. The signal is produced in relation to the presence of analyte in the test solution (col. 2, lines 40-59). The sbp members used in the disclosed test strip device include antigen/antibody pairs and the signal producing system entails the use of a label reagent, such as an enzyme, on the sbp members (cols. 4-5). Production of the test strip device entails contacting the bibulous support with a solution containing reagents and allowing the strip to dry (col. 13, lines 38-44). Columns 18-19 disclose a sandwich assay for the detection of hCG (human chorionic gonadotropin).

Giegel et al (U.S. Patent 4,517,288) discloses a matrix for performing immunoassays. The matrix supports a specific defined zone containing a binding material for an analyte. In use, a sample is applied to the defined zone on the matrix, a labeled indicator which can be correlated to the amount of analyte in the zone is applied, a solvent is applied to the center of the zone to effect a radial chromatographic separation of unbound labeled indicator from the zone, and the amount of labeled indicator remaining in the zone is determined (col. 2, lines 43-68). The binding material on the matrix is generally an antibody specific for the analyte (col. 3, lines 35-36). To prepare the matrix, an antibody solution is applied to the matrix and the sheet is dried (col. 4, lines 26-28). Columns 4-6 disclose sandwich and competitive immunoassays. The label in the labeled indicator can be an enzyme or a fluorescent label. Measuring the labeled indicator can be done with a reflectometer (col. 6, line 28).

Rupchock et al (U.S. Patent 4,447,526) discloses a matrix for use in immunoassays. Preparation of the matrix entails applying immunoreagents (antigens or antibodies) to the matrix and drying the matrix (col. 8, lines 19-21).

It would have been obvious to one of ordinary skill in the art to dehydrate the reagents recited in the device of Count 1, as taught by Deutsch et al or Weng et al or Giegel et al or Rupchock et al, because Deutsch et al, Weng et al, Giegel et al, and Rupchock et al all show it to be conventional in the test device art to dry/dehydrate reagents onto a test support. Furthermore, drying of the reagents provides the advantage of convenient storage of the test device prior to its use.

With respect to the use of antigen and antibody reagents in the device of Count 1, it would have been obvious to one of ordinary skill in the art to use such reagents, as taught by Deutsch et al or Weng et al or Giegel et al or Rupchock et al, in the device of Count 1 because the broad language of Count 1 is generic with respect to the type of reagents that can be used in the disclosed device and Deutsch et al, Weng et al, Giegel et al, and Rupchock et al show that the use of antigen and antibody reagents in test devices such as the test device of Count 1 is conventional in the art. Moreover, the highly specific nature of antibodies makes the device of Count 1 more sensitive for the detection of analytes.

With respect to claim 42, Weng et al and Giegel et al show it to be conventional in the art to use enzymes as label reagents in immunoassays and thus would have been an obvious choice of label to one of ordinary skill in the art to use in the labeled reactant of the device of Count 1.

16. Claims 41, 46, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Count 1 from the interference proceedings in view of Deutsch et al or Weng et al or Giegel et al or Rupchock et al as applied to claims 35, 36, 38, 40, 42-45, and 48-50 above, and further in view of Kondo et al.

See above for the teachings of Count 1, Deutsch et al, Weng et al, Giegel et al, and Rupchock et al.

The combination of Count 1, Deutsch et al, Weng et al, Giegel et al, and Rupchock et al differs from the instant invention in failing to teach the detection of hCG.

Kondo et al (U.S. Patent 4,496,658) teaches the detection of hCG by immunoassay. Detection of hCG is a technique commonly utilized as an early diagnostic procedure for pregnancy. Furthermore, in chorionic diseases such as hydatidiform mole, destructive mole, villous cancer, etc determination of hCG in the urine, blood or other body fluid has proved to be very beneficial for an early detection of such disorders, evaluation of effects of treatments and prognostic management of the diseases (col. 1, lines 10-19). A sandwich enzyme immunoassay for the detection of hCG is disclosed in col. 7, lines 56-68.

It would have been obvious to one of ordinary skill in the art to modify the device of Count 1 for the detection of hCG, as taught by Kondo et al, because Kondo et al teach that hCG is an analyte of medical importance for the detection of pregnancy and certain diseases. Furthermore, Kondo et al shows that hCG can be detected by as immunoassay such as the immunoassay that would be performed in the device of Count 1 and Deutsch et al and Weng et al

show that hCG can be detected by immunoassays on test strip devices such as the device of Count 1.

17. Claims 51-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Count 1 from the interference proceedings in view of Kondo et al.

See above for the teachings of Count 1.

The device of Count 1 differs from the instant invention in failing to teach a sandwich immunoassay for the detection of hCG and the use of an enzyme label in the labeled reactant.

See above for the teachings of Kondo et al.

It would have been obvious to one of ordinary skill in the art to modify the device of Count 1 for the detection of hCG, as taught by Kondo et al, because Kondo et al teach that hCG is an analyte of medical importance for the detection of pregnancy and certain diseases and Kondo et al shows that hCG can be detected by an immunoassay such as the immunoassay provided for by the device of Count 1.

With respect to the use of enzymes as a label in an immunoassay, Kondo et al shows it to be conventional in the art to use enzymes as label reagents in immunoassays and thus would have been an obvious choice of label to one of ordinary skill in the art for use in the labelled reactant in the device of Count 1.

18. Claims 36, 37, 39-42, 46, 47, 51-54, 56, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deutsch et al in view of Kondo et al and Tom et al.

See above for the teachings of Deutsch et al.

Deutsch et al differs from the instant invention in failing to teach a sandwich immunoassay for the detection of hCG, the use of an enzyme label in the labeled reactant, and the specific assay formats recited in claims 37 and 39.

See above for the teachings of Kondo et al.

Tom et al (EP 0 046 004) disclose a test strip for performing competitive and sandwich immunoassays. Table 1 on page 12 teaches all of the possible competitive and sandwich assay formats that can be performed in the disclosed test strip.

It would have been obvious to one of ordinary skill in the art to modify the device of Deutsch et al for a sandwich immunoassay to detect hCG, as taught by Kondo et al, because Tom et al teaches that competitive and sandwich assays are equivalent assay formats for the detection of analytes (antigen or antibody) on test strips such as the test strip of Deutsch et al and Deutsch et al teaches the detection of hCG in general in column 9, line 26.

With respect to claims 37 and 39, those specific assay formats are shown by Tom et al to be conventional assay formats and thus obvious alternatives to the assay format(s) taught by Deutsch et al, depending on the analyte (either antigen or antibody) that is to be detected.

19. Claims 37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Count 1 from the interference proceedings in view of Deutsch et al or Weng et al or Giegel et al or Rupchock et al as applied to claims 35, 36, 38, 40, 42-45, and 48-50 above, and further in view of Tom et al.

See above for the teachings of Count 1, Deutsch et al, Weng et al, Giegel et al, and Rupchock et al.

The combination of Count 1, Deutsch et al, Weng et al, Giegel et al, and Rupchock et al differs from the instant invention in failing to teach the specific assay formats recited in claims 37 and 39.

See above for the teachings of Tom et al.

The specific assay formats recited in instant claims 37 and 39 are shown by Tom et al (Table 1 on page 12) to be conventional assay formats and thus would have been obvious alternatives to the assay format recited in Count 1, depending on the analyte (either antigen or antibody) that is to be detected.

20. Claims 36, 40, 41, 42, 46, 47, and 51-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Count 2 from the interference proceedings in view of Kondo et al.

See above for the teachings of Count 2.

The device recited in Count 2 differs from the instant invention in failing to teach a sandwich immunoassay for the detection of hCG or the use of an enzyme label in the labeled reactant.

See above for the teachings of Kondo et al.

It would have been obvious to one of ordinary skill in the art to modify the device recited in the method of Count 2 for a sandwich immunoassay for the detection of hCG, as taught by Kondo et al, because Kondo et al teach that hCG is an analyte of medical importance for the detection of pregnancy and certain diseases and Kondo et al shows that hCG can be detected by immunoassays such as the immunoassay provided for by the device of Count 2.

With respect to the use of enzymes as a label, Kondo et al shows the use of enzymes as label reagents in immunoassays is well known and conventional in the immunoassay art and thus would have been an obvious choice of label to one of ordinary skill in the art.

21. Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Count 2 from the interference proceedings in view of Tom et al.

See above for the teachings of Count 2.

The device recited in Count 2 differs from the instant invention in failing to recite the specific assay formats recited in instant claims 37-39.

See above for the teachings of Tom et al.

It would have been obvious to one of ordinary skill in the art to modify the device recited in Count 2, as taught by Tom et al, to reflect the specific assay formats recited in instant claims 37-39, because Tom et al shows that these are all well known and conventional assay formats which can be performed in devices like those disclosed in Tom et al and Count 2.

Conclusion

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is 308-3991. The examiner can normally be reached on Monday-Thursday from 9:30 am to 7:00 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.

cchin/cc
July 16, 2002

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641